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10/815,421	03/31/2004	Syed F.A. Hossainy	50623.359	7688
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Cameron K. Kerrigan		EXAMINER		
Squire, Sanders & Dempsey L.L.P.		SILVERMAN, ERIC E		
Suite 300				
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San Francisco, CA 94111		1615		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/815,421

Applicant(s)

HOSSAINY, SYED F.A.

Examiner

Eric E. Silverman, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) 1-30, 42-46, 50 and 53-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-41, 47-49, 51 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10-12-04
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicants' response to the election/restriction requirement was received and entered on 8/13/2007. Applicants' elected Group II, claims 31 – 57 without traverse. Applicants further elected PBMA as the species of structural component and PEG-PBMA-PEG as the biobeneficial component. Applicants aver that claims 31 – 49 and 51 – 57 read on the elected species. Since no error was alleged in the election requirement, the election of species is deemed to be **without traverse**. Note that the claims set entered 8/13/2007 incorrectly uses the status modifier "original" for claim 50. Future claim sets should indicate this claim to as "withdrawn".

Claims 42 – 46 and 53 – 57 do not read on the elected species. The elected biobeneficial component, PEG-PBMA-PEG does not contain any of the peptides of claim 42, nor the polysaccharides of claim 43 – 45, nor the sulfonic acid derivatives of claim 46. Nor does the elected species include the structure of claim 52, upon which claims 53 – 57 depend. Examiner contacted Applicants representative on 9/17/2007 in an attempt to reach an agreement about the status of these claims. See the attached interview summary for details of the conversation. No agreement was reached, however, because claims 42 – 46 and 53 – 57 do not read on the elected species, these claims are nonetheless withdrawn from consideration.

Future claim listings should indicate the withdrawal of claims 42 – 46, 50, and 53 – 57.

Priority

It is noted that this Application claims benefit of copending US Application No. 10/317,435, filed 12/11/2002. However, the copending application does not have support for the elected PEG-PBMA-PEG biobeneficial agent. Accordingly, the actual filing date of this application, 3/31/2004, is the effective filing date.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39 – 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 states, in pertinent part, “AB-, ABA-, BAB-, ABC-, or ABCBA- block copolymers.” It is unclear what is meant by the dash in this notation. For example, it is not clear how an “AB-” block copolymer is different from an “AB” block copolymer.

In claim 40, it is not clear what is encompassed by “fragments derived from poly(alkylene glycols)”, nor is it clear what is included in “derivatives of sulfonic acid”. The artisan would not know what fragments are “derived from” or are “derivatives of” the named compounds, and thus would be unable to determine the metes and bounds of the claimed invention.

Claim 41 lacks antecedent basis for “the poly(alkylene glycols)” in claim 40. Claim 40 recites “fragments derived from poly(alkylene glycols)”.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31 – 41, 47 – 49, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,110,483 to Whitbourne et al. in view of WO 2004/101018, of record.

I. Claim interpretation

It is recognized that Applicants may be their own lexicographer. In the instant application, Applicants have used an unusual definition for block copolymers. In the discussion of the nature of the copolymer blocks (pages 4 – 5 of the specification), Applicants explicitly state “The[se] blocks *need not be linked at the ends*, . . .” (emphasis added).

Using Applicants’ definition, a physical mixture of the homopolymers corresponding to the various blocks of a block copolymer is a block copolymer where the blocks are not linked at the ends.

While it is recognized that this is not the typical definition of a block copolymer in the art, Applicants’ right to be his or her own lexicographer is not abridged so long as the atypical definition is clear so as to put readers on notice. In this case, the definition is clear, and readers are put on notice, as to the atypical use of the term “block copolymer”.

II. Reason for the rejection

The claims require a medical device, specifically a stent, with a two-part coating. The coating must contain a structural component, for which Applicants elected PBMA (poly (butyl methacrylate)), and a biobeneficial component, for which Applicants elected PEG-PBMA-PEG. Dependent claims specify the ratio of the two components.

Whitbourne teaches stents coated with PBMA (claim 7).

Whitbourne does not teach the use of PEG-PBMA-PEG.

The WO reference teaches the use of PBMA and PEG as a topcoat for a polymer coated stent (examples 4 and 5). The PEG and PBMA form an interpenetrating polymer mixture, which suffices to read on the elected PEG-PBMA-PEG block copolymer according to Applicants' definition of block copolymer in the instant specification. The topcoat has the advantage of providing a controllable release of a drug in the stent (see Fig. 4, description thereof, and examples).

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use the topcoat composition of WO on the PBMA coated stent of Witbourne. The motivation is to control the drug release rate. With regard to the ratio of components, this is a matter of mere optimization, wherein the artisan would find the best ratio depending on the desired use. Since WO teaches how to make and provide the topcoat to a stent, the artisan would enjoy a reasonable expectation of success.

Conclusion

No claims are allowed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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